IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
Eastern Division

LMR HOME HEALTH CARE, INC. Plaintiff, v. XAVIER BECERRA, SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES Defendant.	)	Civil Action No.: _____

COMPLAINT FOR JUDICIAL REVIEW

Plaintiff, LMR Home Health Care, Inc. ("LMR"), by and through its undersigned legal counsel, hereby files this Complaint for Judicial Review against Defendant, Xavier Becerra, in his official capacity as the Secretary of the U.S. Department of Health and Human Services ("Secretary"), following the final agency decision of the Medicare Appeals Council ("Council") as to Council docket numbers M-24-891 and M-24-923 and Office of Medicare Hearings and Appeals (OMHA) appeal number 3-12204613354 and in support thereof states as follows:

PRELIMINARY STATEMENT

1. LMR, a Medicare-enrolled home health care provider, challenges the Secretary's assessment that it has been overpaid by hundreds of thousands of dollars for reasonable and necessary in-home therapy and nursing services furnished from 2017 to 2019.

2. The Secretary's determination rests on a flawed, unreliable, and incomplete statistical sampling methodology used to extrapolate the alleged overpayment.

3. The Secretary has, moreover, erroneously applied the coverage rules for home

health services in reaching his decision that 8 claims for services rendered by LMR should not be reimbursed by Medicare.

4. The Court's review of the administrative record will disclose that the Secretary's final decision, as issued through the Council, is not supported by substantial evidence and fails to properly apply the governing law. The Court should accordingly reverse (and/or remand) the Secretary's overpayment determination.

PARTIES

5. LMR is a corporation organized under the laws of the State of Illinois. LMR's principal place of business is located at 167 West Boughton Road, Bolingbrook, IL 60440.

6. Xavier Becerra is the Secretary of the U.S. Department of Health and Human Services (HHS) and the proper Defendant in this action pursuant to 42 C.F.R. § 405.1136(d)(1).

JURISDICTION AND VENUE

7. The Court has jurisdiction over this action pursuant to 42 U.S.C. § 1395ff(b)(1)(A) (incorporating by reference 42 U.S.C. § 405(g)), which authorizes judicial review of a final agency decision rendered by the Secretary.

8. Venue is proper pursuant to 42 U.S.C. § 1395ff(b)(1)(A) because LMR's principal place of business is located in this judicial district.

9. The amount in controversy exceeds the jurisdictional requirement set forth at 42 U.S.C. § 1395ff(b)(1)(E)(i).

10. This action has been initiated within 60 days of the final agency decision dated March 8, 2024, as required by 42 C.F.R. §§ 405.1130 and 405.1136(c)(1).

MEDICARE COVERAGE OF HOME HEALTH SERVICES

11. Medicare is the federal health insurance program for the elderly and disabled

established in 1965. The Medicare statute is codified at 42 U.S.C. § 1395 *et seq.*

12. The Medicare program is administered by the Centers for Medicare and Medicaid Services (CMS), which is an agency within HHS.

13. Home health services include but are not limited to nursing care, physical therapy, occupational therapy, speech therapy, medical social services, and home health aide care furnished to patients who, due to illness or injury, are confined to their homes.

14. Medicare covers reasonable and necessary home health services furnished to eligible beneficiaries. To qualify for the Medicare home health benefit, a beneficiary must require "skilled" care on an intermittent (i.e., less-than-daily) basis, be confined to the home, and be under the care of a physician who certifies his or her eligibility for home care.

15. A beneficiary will be considered homebound where he or she has a condition due to illness or injury that restricts his or her ability to leave home, except with the aid of a supportive device (e.g., a cane or walker), special transportation, or another person. A beneficiary will also be considered homebound if leaving the home would be medically contraindicated. The beneficiary's condition should be such that leaving home would require a considerable and taxing effort and that the beneficiary is normally unable to leave home.

16. A beneficiary must be under the care of a physician who certifies that he or she is confined to the home and requires intermittent skilled care. The physician must establish and periodically review a plan of treatment for the home health services. The physician's certification must be accompanied by documentation of a face-to-face encounter with the beneficiary that corroborates the beneficiary's homebound status and need for skilled care.

17. Home health services must be "skilled" according to Medicare coverage guidelines. A "skilled" service is one that is so inherently complex that it can only be safely and

effectively rendered by licensed or technical personnel, such as nurses or therapists.

18. To be covered by Medicare, skilled nursing services must be reasonable and necessary for the treatment of a beneficiary's illness or injury in the context of that beneficiary's medical condition. The services must be consistent with the nature and severity of the patient's condition, unique medical needs, and accepted standards of medical and nursing practice.

19. Beneficiaries are entitled to receive skilled nursing care for conditions that are acute, chronic, terminal, or expected to last a long time.

20. To be covered by Medicare, skilled therapy services must be: (1) considered under accepted standards of medical practice to be safe and effective treatment for the beneficiary's condition; (2) provided with the expectation that the beneficiary's condition will improve in a reasonable and generally predictable period of time; and (3) provided in an amount and at a frequency and duration that is reasonable.

21. CMS regulations at 42 C.F.R. § 409.33 and sub-regulatory guidance in Chapter 7 of the Medicare Benefit Policy Manual set forth several examples of skilled nursing services that are covered under the Medicare home health benefit, including but not limited to observation and assessment of a beneficiary's condition or teaching and training activities.

22. Nursing services for observation and assessment are covered by Medicare where the skills of a licensed nurse are required to identify and evaluate the potential for a complication or acute change in a beneficiary's condition.

23. Nursing services for teaching and training are covered by Medicare where the skills of a licensed nurse are required to instruct a beneficiary (or the beneficiary's caregiver) as to management of his or her treatment regimen.

24. CMS regulations at 42 C.F.R. § 409.33 and sub-regulatory guidance in Chapter 7

of the Medicare Benefit Policy Manual set forth examples of skilled therapy services that are covered under the Medicare home health benefit, including but not limited to evaluation of a beneficiary's functional status, therapeutic exercises, gait training, and range of motion exercises.

MEDICARE CLAIM AUDITS AND APPEALS

25. CMS contracts with private entities to perform various functions on its behalf, including but not limited to provider and beneficiary enrollment, claims processing, medical review audits, and adjudication of administrative claim appeals.

26. Medicare claims are processed by contractors called Medicare Administrative Contractors (MACs). Claim audits are undertaken by several different CMS contractors, including but not limited to Unified Program Integrity Contractors (UPICs). MACs, along with separate contractors known as Qualified Independent Contractors (QICs), are also responsible for handling administrative claim appeals.

27. CMS' contractors may perform claim audits on a pre-payment or post-payment basis to ensure claims meet applicable Medicare criteria for coverage and reimbursement. If a claim is denied on a pre-payment basis, then the provider receives reimbursement. If a claim is denied on a post-payment basis, then the provider is responsible for repaying any resulting overpayment.

28. Most Medicare claims are not subject to review prior to payment, although CMS has implemented prior authorization-type programs for certain categories of items or services.

29. On June 1, 2019, CMS implemented the Review Choice Demonstration (RCD) program for all Illinois-based home health agencies. According to CMS, the purpose of RCD is to, "…help[] ensure that the right payments are made at the right time for home health services through either pre-claim or post-payment review, protect[] Medicare funding from improper

payments, reduce[] the number of Medicare [claim] appeals, and improve[] provider compliance with Medicare program requirements."

30. Toward that end, CMS created several different claim review options, and every home health agency in Illinois is required to select one demonstration option and comply with the corresponding requirements for six-month "cycles." One of the available claim review options under RCD is called Pre-Claim Review (PCR).

31. At all times relevant hereto, LMR selected PCR as its choice for RCD. Under PCR, home health providers are required to submit medical records supporting their claims to the MAC for review prior to payment. If the contractor determines that the records do not comply with CMS coverage criteria for home health services, it will not make payment for the claim. If the contractor finds the applicable coverage guidelines have been met, then it will process and pay the claim.

32. The first RCD cycle for Illinois started on June 1, 2019 and ended on November 30, 2019. For providers who elected to participate in PCR, the first RCD cycle covered all claims with dates of service on or after June 1, 2019.

33. Providers who are dissatisfied with any pre- or post-payment adverse claim determination (when made as part of the RCD program or through any other type of CMS audit) may contest that decision through a four-step administrative appeals process.

34. The four steps in CMS' administrative claim appeal process are: redetermination, reconsideration, a hearing before an Administrative Law Judge (ALJ), and review by the Council.

35. Requests for redetermination are processed by MACs. Requests for reconsideration are handled by QICs. Hearing requests are adjudicated by ALJs housed within OMHA. The Council is a component of the Departmental Appeals Board of HHS, and the

Council is responsible for issuing final agency decisions as to Medicare reimbursement disputes on behalf of the Secretary.

STATISTICAL SAMPLING FOR OVERPAYMENT ESTIMATION

36. Due to the large volume of claims submitted to the Medicare program for payment each year, it is in most cases neither feasible nor practical for CMS' contractors to perform post-payment audits of individual claims.

37. In 1986, CMS issued an administrative ruling establishing its right to utilize statistical sampling methodologies to project or "extrapolate" overpayments to providers upon review of a statistically valid sample of a provider's claims.

38. Medicare guidelines for sampling and extrapolation are contained in Chapter 8 of the Medicare Program Integrity Manual (MPIM). The provisions of the MPIM are binding on UPICs.

39. According to the MPIM, the major steps in statistical sampling are: (1) identifying the provider; (2) selecting the period to be reviewed; (3) defining the universe and the sampling unit and constructing the sampling frame; (4) assessing the distribution of the paid amounts in the sample frame to determine the sample design; (5) performing the appropriate assessments to determine whether the sample size is sufficient for the statistical analyses used, and identifying the corresponding confidence interval; (6) designing the sampling plan and selecting the sample from the sampling frame; (7) examining each of the sampling units to determine if there was an overpayment or an underpayment; and (8) estimating the overpayment (i.e., projecting the overpayment to the universe of claims).

40. The "universe" of a provider's Medicare claims consists of all claims submitted by the provider within a certain timeframe. The contractor then applies various limiting criteria

to the universe based on the nature and scope of its audit. For example, the contractor may wish to limit the population of claims to only certain types of claims or claims for certain services.

41. CMS guidelines state that any claims or service that have been subject to prior review "are not utilized in the construction of the sample frame."

42. Once the limiting criteria are applied to the universe, the resulting dataset is called the "sampling frame." The sampling frame is an ordered list of all possible sampling units. The sampling units are the claims or individual services to be reviewed during the audit.

43. The sampling units are chosen from the frame using a series of random numbers generated by a computer algorithm. In cases where the sampling unit is the claim, the random numbers produced by the computer algorithm are matched with the position numbers of the claims in the sampling frame. The claims matched in this manner are chosen to serve as the claims comprising the sample.

44. Once the sample of claims is constructed, each claim is reviewed by the contractor's medical review staff. The reviewer may determine that a claim was correctly paid, incorrectly paid, or that it should be paid at a different amount from that which was billed by the provider.

45. Upon completion of the medical records review, the contractor's staff calculates the amount by which the provider was overpaid for the sampled claims. The projected overpayment amount is then calculated by multiplying the mean net overpayment amount from the sample by the total number of sampling units in the frame.

46. Medicare contractors are required to maintain complete documentation of the sampling methodology that is utilized in each case. This documentation includes, but is not limited to the universe, sampling frame, sampling plan, and series of random numbers used in the

sample selection process.

47. When contesting an extrapolated overpayment determination through the Medicare claim appeal process, a provider has a right to challenge the accuracy or validity of the contractor's sampling methodology.

48. CMS manual instructions require contractors to maintain all data files and workpapers related to an extrapolated overpayment determination in the event the sampling methodology is challenged on appeal. These files must be sufficient to enable independent replication of the sampling frame, sample of claims, and extrapolated overpayment amount. CMS also requires its contractors to make all such data files and work papers available to providers for review.

49. When sampling for the purposes of extrapolation, Medicare contractors are required to draw a statistically valid random sample and utilize only statistically valid methods to project an overpayment.

FACTUAL AND PROCEDURAL OVERVIEW

50. At all times relevant hereto, LMR was a Medicare-certified provider of home health services. LMR provides high quality home health services to the residents of the Chicagoland area, many of whom are Medicare beneficiaries.

51. At all times relevant hereto, CoventBridge Group, Ltd. ("CoventBridge") was a UPIC whose jurisdiction included the State of Illinois.

52. In a letter dated August 20, 2021, CoventBridge provided notice of its intent to conduct a post-payment audit of certain claims for home health services billed by LMR to the Medicare program between 2017 and 2019. This audit covered 34 claims for services rendered to 33 different Medicare beneficiaries. LMR submitted copies of its medical records to the UPIC.

53. In a letter dated January 27, 2022, CoventBridge alleged that all the claims under review failed to meet Medicare coverage criteria in whole or in part. The UPIC further asserted that the claims it reviewed constituted a statistically valid sample of LMR's claims for the audit period in question and thereby extrapolated a Medicare overpayment in the amount of $4,423,191.27.

54. To extrapolate the alleged overpayment, CoventBridge utilized a non-standard sampling methodology called the Minimum Sum Method. When calculating the alleged overpayment, the UPIC failed to perform a mathematical calculation required for use of the Minimum Sum Method. As a result of this error, the initial overpayment assessment was inflated by $868,000.

55. When constructing the sampling frame, the UPIC purports to have removed from the universe a set of claims from an "exclusion file." CoventBridge's sampling plan did not elaborate on the origin of this "exclusion file" or otherwise explain what claims were contained within it.

56. CoventBridge failed to remove claims subject to prior review, such as those reviewed under PCR, from the sampling frame, as required by Medicare guidelines for statistical sampling.

57. Along with the overpayment determination notice, the UPIC produced to LMR copies of its data files in support of the extrapolation. These data files did not include the universe or the referenced "exclusion file."

58. LMR promptly filed a request for redetermination with Palmetto GBA, the responsible MAC. In a partially favorable notice of redetermination dated July 19, 2022, the MAC overturned two unfavorable claim determinations but affirmed all other aspects of the

extrapolated overpayment assessment.

59. LMR then sought reconsideration with the appropriate QIC, Maximus Federal Services ("Maximus"). On or around March 14, 2023, the QIC rendered a partially favorable reconsideration decision that reversed 14 unfavorable claim decisions in full and one claim decision in part. Maximus agreed with the remaining adverse claim determinations and upheld CoventBridge's use of statistical sampling to calculate the alleged overpayment.

60. LMR requested a hearing before an ALJ to challenge the unfavorable aspects of the QIC's reconsideration decision. The ALJ to whom the case was assigned held an evidentiary hearing on August 1, 2023. LMR presented four witnesses who testified regarding various administrative, clinical, and statistical issues relevant to the case.

61. In a partially favorable hearing decision dated October 10, 2023, the ALJ reversed two claim denials and upheld the remaining 16 claim denials. The ALJ further determined that CoventBridge's sampling methodology was statistically invalid and accordingly ordered the contractor to recompute the alleged overpayment based on the actual amounts of the remaining denied claims.

62. On December 8, 2023, LMR asked the Council to review the remaining unfavorable claim determinations from the ALJ's decision.

63. In a memorandum dated December 11, 2023, CMS urged the Council to reverse the ALJ's decision to set aside the extrapolated overpayment. In a responsive submission dated December 29, 2023, LMR asked the Council to affirm the ALJ's ruling as to the extrapolation.

64. In a consolidated decision dated March 8, 2024, the Council reversed three adverse claim determinations, found that LMR was not liable for overpayments associated with five claims, and reinstated the extrapolated overpayment. In so doing, the Council instructed the

contractor to use a new sampling methodology to project the alleged overpayment. The Council also affirmed eight unfavorable claim decisions.

65. The Council's decision did not require the contractor to utilize a specific methodology or otherwise set forth any parameters for the recalculation of the overpayment.

66. Upon information and belief, the administrative record reviewed by the Council did not contain the universe or the "exclusion file" used by CoventBridge in construction of the sampling frame.

67. The Council upheld the denial of claims for nursing and/or physical therapy services provided to beneficiaries R.A. (03/08/18 – 05/03/18), M.C. (12/17/18 – 02/15/18), E.J.C. (11/21/18 – 01/15/19), M.L. (03/07/19 – 05/05/19), L.P. (08/28/17 – 10/23/17), L.S. (07/07/17 – 09/14/17 and 11/16/18 – 01/14/19), and M.W. (12/22/17 – 01/15/18) on the bases that the services were not skilled and otherwise failed to met CMS coverage requirements for home health services.

68. The Council's unfavorable coverage determinations are incorrect because the supporting medical records establish that the nursing and physical therapy services provided to the beneficiaries were sufficiently complex such that they could only have been safely and effectively rendered by licensed personnel.

69. The Council's unfavorable coverage findings are also inconsistent with CMS regulations. For example, nothing in the applicable coverage guidelines requires beneficiaries to suffer a new illness or injury at the time of recertification to establish Medicare coverage for home health services. Similarly, nothing in the law precludes a nurse or therapist from furnishing the same or similar services to a beneficiary across multiple visits or certification periods, so long as those services are reasonable and necessary.

70. The MAC sent a notice to LMR dated March 29, 2024 stating that an overpayment in the amount of $664,367 had been recalculated based on the Council's decision. This correspondence did not include any explanation for or data associated with the re-extrapolated overpayment amount.

71. On April 16, 2024, LMR, acting through counsel, submitted a request under the Freedom of Information Act (FOIA) to CMS seeking all data, workpapers, and other files used in the recalculation of the alleged overpayment. To date, CMS has not produced any materials in response to LMR's FOIA request.

72. The Council's decision is the final agency decision in this matter pursuant to 42 U.S.C. § 1395ff(b)(1)(A). LMR has thus exhausted its administrative remedies, and this case is eligible for judicial review.

COUNT I – CORRECT LEGAL STANDARDS

73. Plaintiff hereby incorporates by reference paragraphs 1 through 72 herein.

74. The Council's decision to uphold the extrapolated overpayment is inconsistent with the relevant legal standards because the administrative record does not contain all the data files necessary to recreate the contractor's sampling methodology.

75. The Council's decision to uphold the extrapolated overpayment is inconsistent with the relevant legal standards because the sampling frame was not constructed according to CMS requirements.

76. LMR has been denied its right to challenge the contractor's new sampling methodology used for the first time to recalculate the overpayment based on the Council's decision.

77. The Council's decisions upholding the denial of claims for services rendered to

beneficiaries R.A. (03/08/18 – 05/03/18), M.C. (12/17/18 – 02/15/18), E.J.C. (11/21/18 – 01/15/19), M.L. (03/07/19 – 05/05/19), L.P. (08/28/17 – 10/23/17), L.S. (07/07/17 – 09/14/17 and 11/16/18 – 01/14/19), and M.W. (12/22/17 – 01/15/18) is inconsistent with the relevant legal standards governing Medicare coverage of home health services.

COUNT II – SUBSTANTIAL EVIDENCE

78. Plaintiff hereby incorporates by reference paragraphs 1 through 72 herein.

79. The Council's decision upholding the extrapolated overpayment is unsupported by substantial evidence because the administrative record does not contain sufficient information to recreate the sampling frame.

80. The Council's decision upholding the denial of claims for home health services rendered to beneficiaries R.A. (03/08/18 – 05/03/18), M.C. (12/17/18 – 02/15/18), E.J.C. (11/21/18 – 01/15/19), M.L. (03/07/19 – 05/05/19), L.P. (08/28/17 – 10/23/17), L.S. (07/07/17 – 09/14/17 and 11/16/18 – 01/14/19), and M.W. (12/22/17 – 01/15/18) is unsupported by substantial evidence because the medical records establish that the nursing and/or therapy services in question were so complex that they could have only been safely and effectively provided by licensed personnel.

81. No reasonable mind would accept the evidence cited by the Council in its unfavorable coverage decisions as sufficient to support the conclusion that the corresponding claims are not covered by Medicare.

82. In reaching the eight unfavorable coverage determinations referenced herein, the Council has failed to appropriately consider the evidence that fairly detracts from its decisions.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court:

83. Reverse the Council's decision upholding the use of statistical sampling to extrapolate the alleged Medicare overpayment.

84. Reverse the Council's decisions denying Medicare coverage for the home health services provided to the following beneficiaries on the relevant dates of service: R.A. (03/08/18 – 05/03/18), M.C. (12/17/18 – 02/15/18), E.J.C. (11/21/18 – 01/15/19), M.L. (03/07/19 – 05/05/19), L.P. (08/28/17 – 10/23/17), L.S. (07/07/17 – 09/14/17 and 11/16/18 – 01/14/19), and M.W. (12/22/17 – 01/15/18).

85. Remand the case to the agency with instructions to provide LMR with an opportunity to contest the new sampling methodology used by CMS' contractor to project the alleged overpayment for the first time following the Council's decision.

86. Award LMR all costs and attorneys' fees for this action as allowed under applicable law.

87. Grant to LMR any other legal or equitable relief that the Court may deem just and proper.

Respectfully Submitted,

Dated: May 6, 2024

/s/ Adam L. Bird
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